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Reassessing the Scope of Federal Biotechnology Oversight

Peter Mostow*

The federal regulation of biotechnology is governed by a comprehensive policy recently promulgated by the Office of Science and Technology Policy. This article examines and evaluates the developmental history and structure of this policy for biotechnology. It is the author's opinion that the present policy contains a series of suppositions which work to reduce the degree of information known about engineered organisms and the dangers they may pose. These suppositions are traced to two sources. First, to an excessive concern with the costs of regulation; and second, to an approach which seeks to solve problems of policy judgement through appeals to science. The author argues that this approach misdirects the regulation of engineered organisms, exempting too many of them from regulatory scrutiny. In conclusion, the author proposes

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means of reforming the policy so that the risk assessment process takes account of factors unique to genetically modified organisms and so that the risk management process is capable of tracking the global environmental effects of biotechnology without unduly hampering industry.

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I. Introduction

Recent advances in precise techniques for genetic manipulation have revolutionized the field of biotechnology in a manner akin to the introduction of steam power to the manufacturing process. New techniques have created living bacterial factories that produce medicines such as insulin,¹ plants more resistant to pesticides or pests,² bacteria that protect crops from frost damage,³ and tomatoes with shelf-lives of three weeks.⁴ These advances, however, overlay a millennia-old history. In its cruder forms, biotechnology has been used to produce beer, wine, and cheeses, as well as to selectively breed plants and livestock. Genetic engineering can thus be viewed either as a step in the long evolution of biotechnology or as a radical break, or revolution, in that process. The tension between these two perspectives accounts for much of the controversy surrounding the regulation of biotechnology.

This article focuses on an area of biotechnology commonly known as the "environmental release" of genetically modified organisms. Such organisms may be plants, as is the case with the pesticide resistant plants mentioned above, or they may be microorganisms such as the "ice-minus" strain of bacteria. Unlike insulin-producing bacteria, which carry out production in safely sealed laboratory environments, this class of biotechnology products is useful only in relatively large, unenclosed spaces such as a tobacco field, or oil spill, on the open ocean.⁵

Genetically modified organisms designed for environmental release appear harder to control — and thus potentially

1. THE PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 2-3 (1991) [hereinafter COMPETITIVENESS COUNCIL].

2. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY — FIELD TESTING ENGINEERED ORGANISMS: GENETIC AND ECOLOGICAL ISSUES, OTA-BA-350, 5 (1988) [hereinafter NEW DEVELOPMENTS IN BIOTECHNOLOGY].

3. *Id.* at 7.

4. *U.S. Proposes Deregulating Calgene's Biotech Tomato*, N.Y. TIMES, July 14, 1992, at D4.

5. For a more comprehensive overview of environmental applications of genetically modified organisms, see NEW DEVELOPMENTS IN BIOTECHNOLOGY, *supra* note 2, at 125-33.

more dangerous — than organisms safely contained within a test tube. Ecologists and others point to the possibility that these new organisms might disrupt native ecosystems in irreversible ways.⁶ These organisms have, therefore, received a large share of the regulatory attention directed toward biotechnology.⁷ Indeed, even today, only a very few such organisms have been allowed to progress to the small-scale field testing stage.⁸

Supporters of industry, as well as scientists, have questioned the stringency of the regulation of environmental releases. They make two principal arguments. First, it is asserted that the risks of such organisms are essentially no greater than the risks of non-modified organisms.⁹ Second, it is believed that overregulation is stalling an industry that needs to grow quickly if it is to win the United States a competitive spot in the global biotechnology market.¹⁰ Biotechnol-

6. See, e.g., James M. Tiedje, et al., *The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations*, 70 *ECOLOGY* 298, 301, 304-05 (1989).

7. See generally NEW DEVELOPMENTS IN BIOTECHNOLOGY, *supra* note 2, at 10, table 1.3 (outlining regulatory agency jurisdiction over releases of genetically modified organisms). Although the initial regulatory concern was with genetic engineering per se, the confinement levels attainable in the laboratory quickly assuaged fears. *Id.* at 9. The focus of the debate has therefore shifted to environmental releases (along with topics not touched upon in this article, such as gene therapy — the use of genetic engineering techniques on humans — and the marketing of genetically engineered foodstuffs, such as the tomato mentioned *supra* at note 4).

8. For at least a decade prior to the 1986 Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) [hereinafter Coordinated Framework], deliberate release was essentially prohibited. The initial National Institutes of Health (NIH) Guidelines for Research on Recombinant DNA Molecules strictly prohibited release. 41 Fed. Reg. 27,902, 27,915 (1976). The Guidelines were subsequently amended to give the NIH Director the power to approve releases on a case by case basis. 43 Fed. Reg. 60,108 (1978). The Director began approving releases in 1981, 46 Fed. Reg. 40,331 (1981), but the first two approved experiments were postponed due to technical problems. The third experiment to be approved, a test of an ice-minus strain of bacteria, 48 Fed. Reg. 24,548, 24,549 (1983), was blocked by a lawsuit brought by environmentalists under the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321-4347 (1988). *Foundation on Economic Trends v. Heckler*, 756 F.2d 143 (D.C. Cir. 1985).

9. E.g., NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: A FRAMEWORK FOR DECISIONS 2, 14-15 (1989) [hereinafter NATIONAL RESEARCH COUNCIL, FRAMEWORK FOR DECISIONS].

10. E.g., COMPETITIVENESS COUNCIL, *supra* note 1, at 4-5. See also Isaac Rabino,

ogy regulation, in this view, should involve not only risk analysis, but also cost-benefit analysis.¹¹

The most recent locus of conflict between proponents of strict regulation and proponents of deregulation is the proper scope of federal oversight of deliberate releases. At question is which subset of all genetically modified organisms destined for environmental release should be subject to federal regulation. For example, industry and some scientists have asserted that many genetic modifications make organisms no more dangerous than the parent strain. They argue that certain classes of genetically modified organisms should be exempted from federal oversight altogether.¹² On the other hand, many ecologists and environmentalists criticize the exemption-based approach on the grounds that possible health and environmental effects of genetically modified organisms are potentially catastrophic. They argue that when conditions are uncertain it is unwise to give up all federal oversight through a program of exemptions.¹³

In a document titled Exercise of Federal Oversight within Scope of Statutory Authority (the "Federal Oversight" document), the Office of Science and Technology Policy (OSTP) announced a comprehensive policy for the scope of biotechnology oversight.¹⁴ This new policy states that the risk of genetically modified organisms should be determined by comparing them with past, safe releases of similar, unmodified

The Impact of Activist Pressures on Recombinant DNA Research, 16 SCI., TECH. & HUMAN VALUES 70, 79 (1991) (82% of U.S. scientists surveyed feared U.S. may lose biotechnology competitiveness due to "controversy and litigation").

11. *Id.*

12. *Id.* at 13-14; NATIONAL RESEARCH COUNCIL, FRAMEWORK FOR DECISIONS, *supra* note 9, at 5.

13. Tiedje, et al., *supra* note 6, at 307-11 (suggesting case by case, rather than category by category, review, and advocating scaled down oversight rather than exemptions for less risky organisms). The Office of Technology Assessment (OTA) document falls somewhere between the Ecological Society of America's position and that of the NRC and the Competitiveness Council. In its recommendations, the OTA includes both the exemption and the scaling-down options. NEW DEVELOPMENTS IN BIOTECHNOLOGY, *supra* note 2, at 26-27.

14. Exercise of Federal Oversight within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (1992) (hereinafter "Federal Oversight").

organisms.¹⁵ Once risks have been determined, the level of agency oversight should be such that the social costs of regulating the risk do not exceed the regulation's social benefits.¹⁶ Using this cost-benefit method, the Federal Oversight document asserts that many types of genetically modified organisms pose minimal risks in relation to the costs of regulating them.¹⁷ This suggests that agencies might profitably proceed by exempting broad categories of organisms from federal oversight. Marking something of a watershed, both in recent theoretical trends in biotechnology regulation and in risk assessment generally, the policy contained in the Federal Oversight document has become the focal point of the current debate on the proper regulatory stance toward biotechnology.

This article analyzes the Federal Oversight document. Part II reviews the administrative history of the document. Part III identifies the four propositions on which the Federal Oversight document is based¹⁸ and individually evaluates the theoretical support for each. Part III.A. examines the idea that regulation should focus on the risks of the product organism rather than on the supposed dangers of the process of genetic engineering per se. Part III.B. introduces the concept of "risk-based" regulation on which the Federal Oversight document relies and the cost-benefit approach that the document brings to risk management. Part III.C. questions the Federal Oversight document's method of determining an organism's "familiarity" in order to calculate its risk. Part III.D. analyzes the use of these risk assessment principles in assigning types of organisms to regulatory categories, a strategy likely to be used largely in exempting these organisms from federal oversight.

Drawing on the criticism developed in Part III, Part IV presents a proposal for reforming the approach announced in the Federal Oversight document. First, several aspects of the system of risk assessment could be made more appropriate to

15. *Id.* at 6757.

16. *Id.*

17. *Id.* at 6755.

18. *See infra* text accompanying note 48.

the risks presented by releases of genetically engineered organisms. Generally, this will correct biases toward underestimating the risks of such organisms and will make the political content of any system of risk assessment more transparent. Second, the category approach to risk management should be replaced by a system of general permitting providing both a minimal burden to industry and a continuing federal ability to monitor the long-term and cumulative effects of environmental release biotechnology.

II. Background of the Scope Debate

The lack of a uniform federal policy concerning the scope of biotechnology oversight traces back to 1986 when the Reagan Administration established inter-agency biotechnology regulation under the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework).¹⁹ The Coordinated Framework apportioned responsibility for the regulation of biotechnology among the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the Department of Agriculture (USDA).²⁰ It specified structural systems for the coordination of their respective regulatory activities, and created an inter-agency committee, the Biotechnology Science Coordinating Committee (BSCC), to oversee the process.²¹

In the Coordinated Framework, the OSTP noted that "any proposal to regulate the research and products of genetic manipulation techniques will quickly confront the issue of what organisms should be considered appropriate for certain types of review."²² Individually, each agency published policy statements containing a scope proposal in which the agency detailed its plans for extending its existing regulatory author-

19. Coordinated Framework, 51 Fed. Reg. 23,302, 23,334. For an excellent discussion of the administrative politics of the scope issue since 1986, see Sidney A. Shapiro, *Biotechnology and the Design of Regulation*, 17 *ECOLOGY L.Q.* 1, 27-31 (1990).

20. Hereinafter referred to collectively as "the Agencies."

21. Coordinated Framework, 51 Fed. Reg. 23,302, 23,303-06.

22. *Id.* at 23,306.

ity to include the new technology.²³ Further, the Coordinated Framework document contained a tentative scope proposal for the BSCC, the overseeing agency. This scope proposal suggested federal oversight of two classes of genetically modified organisms: "inter-generic"²⁴ combinations, and "pathogens." In establishing these criteria, the BSCC sought public comment to help assess the validity of their decisions.²⁵ In addition to the public criticisms of the BSCC's scope proposal, the individual agencies themselves also "experienced unanticipated difficulty developing operational definitions for regulatory purposes."²⁶ For example, the scope definition in the EPA's policy statement in the 1984 proposed Coordinated Framework received numerous comments.²⁷ Then, in its 1986 policy statement, the EPA modified its scope definition in a manner not entirely consistent with the BSCC definition discussed above. This definition, applicable to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)²⁸ and the Toxic Substances Control Act (TSCA),²⁹ covered microorganisms used in the environment that "are pathogenic or contain genetic material from pathogens, [or] contain new combinations of traits."³⁰ This scope definition also was the subject of much public criticism.

23. See *id.* at 23,309 (Statement of FDA policy); *id.* at 23,313 (Statement of EPA policy); *id.* at 23,336 (Statement of USDA policy).

24. The term "inter-generic combination" means an organism whose DNA has elements taken from parent organisms in two or more genera. *Id.* This type of derivative organism was thought to be particularly noteworthy because, for the most part, such combinations do not occur in nature.

25. See *id.* at 23,306-07. One of the major controversies which ensued was over the BSCC's decision that an organism modified only through "non-coding regulatory regions" should not be considered "inter-generic" or a "pathogen." *Id.* at 23,307; see generally Shapiro, *supra* note 19, at 27 and n.163 (discussing controversy over BSCC determination). The Proposed Oversight document contains a similar exemption. See *infra* text accompanying notes 38-39.

26. Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. 31,118, 31,119 (1990) [hereinafter Proposed Oversight].

27. See Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880 (1984); Coordinated Framework, 51 Fed. Reg. 23,302, 23,315.

28. FIFRA §§ 2-31, 7 U.S.C. §§ 136-136y (1988).

29. TSCA §§ 2-309, 15 U.S.C. §§ 2601-2671 (1988).

30. Coordinated Framework, 51 Fed. Reg. 23,302, 23,315.

In 1989, the BSCC established a working group to resolve the scope issue.³¹ This group developed several possible approaches, but was unable to reach a consensus on an appropriate definition.³² One of the better scope definitions extended regulatory oversight to "organisms deliberately modified by the introduction into or manipulation of genetic material in their genomes [and also exempted from oversight] five categories of modifications . . . from the total set of such organisms."³³ This definition was brought before the full BSCC, which was similarly unable to reach a consensus,³⁴ but which, nonetheless, forwarded the definition to the OSTP.³⁵ Claiming that the scope issue had policy implications beyond the jurisdiction of the BSCC, the OSTP forwarded the document to The President's Council on Competitiveness.³⁶ The Council on Competitiveness' review produced a proposed scope definition

31. Proposed Oversight, 55 Fed. Reg. 31,118, 31,119.

32. *Id.*

33. *Id.*

34. *Id.*

35. Proposed Oversight, 55 Fed. Reg. 31,118, 31,119-20.

36. *Id.* at 31,120. Presumably the OSTP was concerned that over-regulation might hinder the domestic biotechnology industry. The Council on Competitiveness was created by President Bush on March 31, 1989. As the name suggests, the Council's mission is to help U.S. industry by combatting what President Bush characterized as "the scourge of unnecessary regulation." Kirk Victor, *Quayle's Quiet Coup*, 23 NAT'L J. 1676 (1991). The Council often accomplishes this by reviewing — and perhaps rejecting — proposed agency regulations. For instance, on April 6, 1991, the Council issued a major rewrite of the EPA's regulations promulgated under the 1990 Clean Air Act Amendments, making them significantly weaker. See Nancy Shute, *Unfair Competition*, THE AMICUS J., Summer 1991 at 33. The Council is also reported to have influenced the FDA's recently announced "hands-off" policy on the marketing of genetically engineered foods. See Warren E. Leary, *Gene-Altered Food Held by the FDA to Pose Little Risk*, N.Y. TIMES, May 26, 1992, at A1. In such actions the Council's primary analytic tool is the application of cost-benefit analysis to proposed regulations; this is a strategy dating to President Reagan's Executive Order 12291 of February 17, 1981, which required agencies to do cost-benefit reviews of their own regulations, and which created the Council's predecessor, the Task Force on Regulatory Review.

Although this Article does not purport to criticize the Council directly, the Federal Oversight document, authored largely by the Council, can be read as a virtual laundry list of its favored methods: the application of cost-benefit analysis to regulations which ought to have numerous goals other than efficiency, the heavy reliance on quantitative risk analysis in situations where many of the risks are difficult to quantify, and the exclusion of public input into the regulatory process.

that the OSTP published in July, 1990 entitled, "Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits [the "Proposed Oversight document"]".³⁷ The proposal submitted by the BSCC to the OSTP had been significantly altered by the Council on Competitiveness. For instance, the Proposed Oversight document took as its major goal the identification of categories of organisms that would be *exempt* from federal oversight.³⁸ Although this may at first seem like a superficial jurisdictional maneuver, it actually goes to the core of the substantive principles for regulation of biotechnology. The principles used in classifying organisms as subject or not subject to oversight are the same as the principles used to evaluate the relative risk of those same organisms.³⁹

In February of 1992, the Administration published its final statement on the scope issue in the Federal Oversight document.⁴⁰ This final statement differs from the earlier Proposed Oversight document primarily in that it no longer mentions specific categories of organisms that would likely be exempt from federal oversight, thus giving agencies more freedom to make their own determinations on this issue.⁴¹ On the other hand, the Federal Oversight document advances a more stringent concept of risk management.⁴² Agencies are to exercise oversight authority only to the extent that it is cost effective.⁴³

In skeletal terms, the Federal Oversight document can be summarized as follows. The document first suggests a method for deciding which organisms should be subject to oversight — only those that pose "unreasonable" risks.⁴⁴ Next, the document suggests a particular method for assessing the risks of

37. Proposed Oversight, 55 Fed. Reg. at 31,120-21.

38. *Id.* at 31,120.

39. See NATIONAL RESEARCH COUNCIL, FRAMEWORK FOR DECISIONS, *supra* note 9 (report from which the proposed oversight document draws these principles).

40. Federal Oversight, 57 Fed. Reg. 6753.

41. *Id.* at 6758-59.

42. *Id.* at 6757.

43. *Id.*

44. *Id.* at 6753. "Reasonableness" is defined in cost-effective terms; hence a level of oversight whose costs are greater than its benefits is "unreasonable." *Id.*

genetically modified organisms — determining their comparability, in terms of a specified set of characteristics, to previously released, safe organisms.⁴⁵ Finally, the document recommends that this methodology be used to choose, in particular cases, the appropriate level of oversight.⁴⁶ Further analysis of the Federal Oversight document yields four foundation propositions:

1. Biotechnology regulation should focus on the product organism, not the process by which it was created.
2. Biotechnology regulation should be risk-based; oversight should be exercised at a given level of risk only to the extent a net social benefit is realized.
3. The basis for biotechnology risk assessment should be an organism's familiarity.⁴⁷
4. Principles 1-3 can be used to generate categories of organisms exempt from federal oversight.⁴⁸

The first three propositions are interrelated and support proposition four, which is the "bottom line" of the Federal Oversight document.

III. Critique of the Federal Oversight Document

This section of the article will examine the Federal Oversight document's four propositions. It will begin by reviewing the development of "product over process" as the basis for regulation.⁴⁹ Next will be an examination of how an organism's perceived risk is used as the basis for regulation.⁵⁰ Then

45. *Id.* Although the document phrases this method as a recommendation, and acknowledges the availability of alternative methods, it does not name or describe any alternatives.

46. *Id.* See Proposed Principles, 55 Fed. Reg. 31,118, 31,119.

47. 57 Fed. Reg. 6753, 6756. Technically, what is meant by the concept of familiarity is not just the organism itself, but the "introduction" as a whole. Thus factors such as the environment into which the organism is introduced and the potential for confining the organism once released are taken into account. Proposed Principles, 55 Fed. Reg. 31,118, 31,119.

48. 57 Fed. Reg. 6753, 6756. See 55 Fed. Reg. 31,118, 31,120.

49. For a discussion of product over process, see *infra* notes 53-73 and accompanying text.

50. For a discussion of risk based regulation, see *infra* notes 74-113 and accom-

there will be a review of the methodology under which an organism's familiarity — comparing its risk to that of an organism previously released — is used to determine the organism's risk.⁵¹ Finally, there will be an examination of the category-based approach to regulation under which groups of similar organisms were excluded from regulation.⁵²

A. Product over Process as the Basis for Regulation

1. Development of the Product/Process Debate

When the Coordinated Framework was announced in 1986, there was still some question as to whether recombinant DNA techniques were per se risky.⁵³ In 1984, the EPA proposed a scope definition targeting recombinant organisms for regulation under the pre-manufacturing clearance provisions for "new" substances under the TSCA.⁵⁴ As the EPA noted, in 1986, this proposal was criticized by many who "expressed concern that the Agency was relating a microorganism's potential for risk to the process by which it was made."⁵⁵ Although the EPA modified its scope definition in 1986 to include pathogens and organisms with "new combinations of traits,"⁵⁶ the latter provision was still essentially process-based. It focused on the novelty of combinations achievable with recombinant-DNA (hereinafter R-DNA) techniques, rather than on their risk.

In 1987 the National Academy of Sciences (NAS) published an influential report entitled, "Introduction of Recombinant DNA-Engineered Organisms in the Environment: Key Issues."⁵⁷ The Academy's primary conclusion was that

panying text.

51. For a discussion of familiarity as a method of risk assessment, see *infra* notes 114-30 and accompanying text.

52. See *infra* notes 131-50 and accompanying text.

53. Coordinated Framework, 51 Fed. Reg. 23,302, 23,302-03.

54. Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,886-87; TSCA § 5, 15 U.S.C. § 2604 (1988).

55. Coordinated Framework, 51 Fed. Reg. 23,302, 23,315.

56. *Id.*

57. COMMITTEE ON THE INTRODUCTION OF GENETICALLY ENGINEERED ORGANISMS INTO THE ENVIRONMENT, COUNCIL OF THE NATIONAL ACADEMY OF SCIENCES, INTRODUC-

"[a]ssessment of the risks of introducing R-DNA engineered organisms into the environment should be based on the nature of the organism . . . not on the method by which it was modified."⁵⁸ Two years later, the National Research Council (NRC) published a report, "Field Testing Genetically Modified Organisms: A Framework for Decisions."⁵⁹ This report also adopted the "product not process" formula as a "fundamental principle" guiding its deliberations.⁶⁰ It concluded that "no conceptual distinction exists between genetic modification of plants and microorganisms by either classical methods or by molecular techniques that modify DNA and transfer genes."⁶¹

These two reports became the intellectual touchstones for the subsequent scope debate. In 1989, the BSCC working group, charged with producing a new scope definition, adopted the NRC's conclusions.⁶² The President's Council on Competitiveness also adopted the "product over process" approach.⁶³ The Proposed Oversight document took pains to avoid "the incorrect implication that the use of any particular genetic modification process per se makes a modified organism of greater risk. . . . Such a misconception could inadvertently tend to retard research and the beneficial development of the biotechnology industry."⁶⁴ This principle is adopted by the Federal Oversight document.⁶⁵ Because it concludes that R-DNA techniques are neither per se risky nor a proxy for risk, the document provides that a given organism should be subject to oversight solely on the basis of the characteristics of the organism, not on the process by which it was made.⁶⁶

TION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES (1987) (hereinafter NATIONAL ACADEMY OF SCIENCES, KEY ISSUES).

58. *Id.* at 7.

59. NATIONAL RESEARCH COUNCIL, FRAMEWORK FOR DECISIONS, *supra* note 9.

60. *Id.* at 2.

61. *Id.* at 14.

62. Proposed Oversight, 55 Fed. Reg. 31,118, 31,120.

63. COMPETITIVENESS COUNCIL, *supra* note 1, at 12.

64. Proposed Oversight, 55 Fed. Reg. 31,118, 31,120.

65. Federal Oversight, 57 Fed. Reg. 6753, 6755.

66. *Id.*

2. Critique of the Product over Process Strategy

As a first point of critique, it should be understood that the impetus behind the product over process strategy derives, in part, from the jurisdictional arguments made by agencies in order to protect their authority to regulate biotechnology under existing statutes. In many areas, this authority is certain only within a delimited sphere, not necessarily reflecting the best possible regulatory approach. Agencies must argue that biotechnology is not a radically new or different technology, and that biotechnology products are not dissimilar from products covered by existing regulatory mandates. Under TSCA, for instance, EPA's regulatory authority depends upon characterizing genetically engineered organisms as "chemical substances."⁶⁷ Similarly, most statutes under which biotechnology is regulated are written in a "product over process" model. Such statutes are based on regulating chemicals *irrespective* of their mode of origin.

As a result, the decision to regulate biotechnology under existing statutes strongly hinders any deviation from the product over process model. If a government authority were to claim in a policy statement that the process of genetic engineering was a significant factor in regulating biotechnology, it would in effect be saying that biotechnology regulation was to proceed in a manner not envisioned by statute. Clearly, this would undermine the authority of the agencies under existing statutes. While the Supreme Court has held that agencies would be unlikely to lose in a case challenging their authority

67. See TSCA §§ 2-3, 15 U.S.C. §§ 2601-02 (1988) (stating that purpose of Act is to regulate "chemical substances and mixtures" and defining that term). From the definition of "chemical substances" given in the Act, it seems clear that TSCA regulation of living organisms was not envisioned by Congress.

See generally C. Robert Manor, Note, *Living Organisms as Chemical Substances: The EPA's Biotechnology Policy Under the Toxic Substances Control Act*, 3 RUTGERS COMPUTER & TECH. L.J. 409 (1987) (arguing that TSCA, in its current form, is inappropriate for biotechnology regulation). This is significant because living organisms are incorporated into and processed by the environment in a different manner than are chemicals, and therefore they present different types of risks.

See also Tiedje et al., *supra* note 6, at 305 (arguing that the risks of genetically engineered organisms are fundamentally different from the risks of chemical substances).

to regulate biotechnology,⁶⁸ agencies acquire and maintain legitimacy in many ways other than through the judiciary. Therefore, the problem is that regulation of biotechnology is developing in response to jurisdictional arguments that can be made to protect and project agency authority instead of in response to national policy considerations.

With this background in mind, the product over process formula can be further examined. As previously noted, the Proposed Oversight document asserted that the products of R-DNA techniques are not per se risky.⁶⁹ When stated as an abstract scientific principle this may be true, since it amounts to no more than the plausible assertion that not all genetically modified organisms pose risks greater than the risks of the parent organisms from which they were derived.⁷⁰ However, the product over process formula has not been elaborated in only, or even primarily, a scientific setting. Rather, it has been used in the political context with full awareness of its consequences for regulation. In that context it may be used, not surprisingly, to assert much more than is scientifically justified. Most importantly, given the jurisdictional analysis presented above, the product over process formula has been used to claim that biotechnology does not require any unique or new regulatory attention; that is, no attention beyond that already provided under statutes enacted without biotechnology in mind.⁷¹

The assertion that biotechnology requires no new regula-

68. See *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 845 (1984). Under *Chevron*, Congress is not required to have spoken directly to the exact limits of a government agency's power. It is enough that the agency's extension of its authority under the statute reflects a "reasonable" agency construction of the statute's language and goals. *Id.*

69. Proposed Oversight, 55 Fed. Reg. 31,118, 31,120. See *supra* text accompanying notes 53-66.

70. For example, many genetic modifications involve splicing small "markers" into an organism's genome. In the majority of cases, such markers have no phenotypic effects, and the resulting organism thus presents no greater risks than does the parent strain. Similarly, genetic modification can just as easily make the resulting organism less risky than the parent strain: a cholera bacterium with the "cholera toxin" gene deleted is a good example.

71. Proposed Oversight, 55 Fed. Reg. 31,118-19.

tory attention simply does not follow from the principle that biotechnology is not per se risky. The fact that the process of genetic engineering does not always produce risky organisms does not imply that the risky organisms it does produce present no new or unique types of risk. Thus, while genetically modified organisms might not be per se risky, they might very well have characteristics that make the risks they pose of a sort not easily regulated by the current regimes.

Certain groups of scientists believe this theoretical analysis can be complemented with empirical data suggesting that genetically modified organisms pose novel risks. A scientific working group has recently asserted that "[o]rganisms with novel combinations of traits are more likely to play novel ecological roles."⁷² To assert this is hardly to prove it; but simply establishing the existence of a valid theoretical controversy is enough to make the political extension of the product over process formula look less than principled.

This argument does not challenge the product over process formula's scientific core. Rather, it challenges the political overextension in the regulatory context. The formula should instruct us that the process of genetic engineering is not inherently dangerous; but from that we should not infer that no new regulation is required. Instead, we should follow the example of the Ecology Society of America which, while accepting the product over process formula, cautions against its overextension "because many novel combinations of properties can be achieved only by molecular and cellular techniques, [and] products of these techniques may often be subjected to greater scrutiny than the products of traditional techniques."⁷³

B. Risk-Based Regulation

Along with the product over process formulation, the

72. Tiedje, et al., *supra* note 6, at 300. The specific kinds of risks the ESA has in mind include long-term damage to ecosystems, cumulative and synergistic effects of different strains of genetically engineered organisms, and pleiotropic effects. *Id.* at 304-05.

73. *Id.* at 310-11.

Federal Oversight document adopts the proposition, first asserted in the Proposed Oversight document.⁷⁴ The President's Council on Competitiveness has already endorsed the risk-based approach in its "Report on National Biotechnology Policy,"⁷⁵ and, beyond that, the concept connects to much broader currents in regulatory theory. Throughout the 1980's, risk assessment came to play a more significant role, especially in the field of environmental regulation. The reasons for this are varied. One commentator attributed the shift to theoretical factors, suggesting that "[a] liberal state attempts to maintain neutrality among competing conceptions of the good by focusing on pragmatic considerations and that [e]xisting biotechnology regulation, which has dealt almost entirely with first-order physical effects, is firmly within this tradition."⁷⁶ But, the shift could also be the result of a new administrative stance requiring agencies to base regulations on cost-benefit analyses.⁷⁷ Only a quantitative procedure, like risk assessment, yields data that can be easily incorporated into a cost-benefit calculation. From the Administration's perspective, this legitimizes the regulation.⁷⁸ Similarly, risk assessment holds out the promise of "objective," scientific regulations, regulations that are easier to defend and which, because they tend to seem less directly political, are less likely to become embroiled in political controversy.

74. Federal Oversight, 57 Fed. Reg. 6753, 6756. "The principles for scope are risk based [and that][o]versight is not required for planned introduction experiments unless information concerning the risk posed by the introduction indicates that oversight is necessary. Proposed Oversight, 55 Fed. Reg. 31,118, 31,120.

75. COMPETITIVENESS COUNCIL, *supra* note 1, at 11-15.

76. Richard B. Stewart, *Regulatory Law*, in *THE GENETIC REVOLUTION* 212, 233 (Bernard D. Davis ed., 1991).

77. Exec. Order No. 12,291, 3 C.F.R. § 127 (1981), *reprinted in* 5 U.S.C. § 601 (1988). Section 2(b)-(d) of the Order sets out the goal of balancing a regulation's benefits with its costs. *Id.* Section 3(d) specifies the required elements of the "Regulatory Impact Analysis". *Id.*

78. It should be noted that under Section 3(d)(1)-(3) of Executive Order 12,291, Regulatory Impact Analyses are permitted to take account of "effects that cannot be quantified in monetary terms." *Id.* But the "bottom line" approach endorsed by the Order makes it clear that unquantifiable risks, although they might enter into the equation, will be effective only at the margins.

1. Risk-Based Regulation of Biotechnology

These explanations suggest that the Administration favors risk assessments based upon "hard" and "first-order" sources of risk. As Stewart notes, this has been the case in the field of biotechnology regulation.⁷⁹ Stewart's observation provides an explanation for the product over process formulation, the narrow focus of current risk assessment considers only the first-order risks of biotechnology products, and omits the broader implications of the process by which they were created. The product over process formulation, although it seems to be a fundamental principle only within the confines of biotechnology, is itself a product of a broader trend in contemporary risk assessment.

One of the problems with this particular style of risk assessment is its tendency to give more emphasis — although admittedly not exclusive emphasis — to easily quantifiable risks.⁸⁰ This would be an acceptable approach if it were true that easily quantifiable risks were either the only risks worth regulating, or the risks of greatest magnitude. However, there is no reason to believe that these conditions are satisfied.⁸¹ In the field of environmental law, and especially in the area of

79. Stewart, *supra* note 76, at 212-13.

80. See John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277 (1992).

81. Proponents of quantitative risk assessment might also make an "economics of information" argument here. Quantifying risks requires research to generate the necessary information, which in turn requires more money. A cost/benefit analysis would therefore seem to favor regulation of quantifiable risks, since the benefits gained by regulating hard-to-quantify risks are lessened by the start-up costs of generating necessary information. See generally John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261 (1991) (discussing economics of information in the regulatory process).

This argument does indicate that a cost/benefit consideration of regulating hard-to-quantify risks should take information costs into account, but it hardly amounts to a proof that regulating easily quantifiable risks is always more efficient. Assuming that both sets of risks have similar spectrums of possible marginal gains (e.g., from efficient to inefficient regulated risks), it would always be the case that regulating some of the hard-to-quantify risks would be more efficient than regulating only quantifiable risks. Thus the information costs would in some cases be well-spent, as would perhaps regulation even without the necessary information, if the risks involved seem potentially very serious.

biotechnology, many potential risks are accompanied by substantial uncertainty.⁸² Furthermore, when a risk involves long term effects on complex ecosystems, quantitative assessment can be speculative at best. Unfortunately, quantifiable risks tend to be ignored under the present concept of risk-based regulation.

Another general feature of risk assessment is its tendency to make political or value decisions seem like objective scientific conclusions.⁸³ While this may be of strategic benefit to agencies or elected officials, it has undemocratic implications. Critics have recently advanced the thesis that, appearances to the contrary, quantitative risk assessment is not merely a scientific calculation. Rather, it involves significant value-based decisions.⁸⁴ The thesis includes decisions about how to frame problems, about what sorts of risks will be considered (e.g., aggregate cancers or deaths versus cancer or death rate among maximally affected population), and about which baselines will be used (e.g., how much risk is "acceptable").

The baseline problem is particularly important when a risk assessment is combined with a cost-benefit analysis in formulating a regulation. However, since no satisfactory theory exists for determining a "rational" degree of risk aversion or risk taking, such decisions are often subjective.⁸⁵ Further, a

82. See generally Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 102-03 (1988); see also Note, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553 (1986).

83. See Latin, *supra* note 82, at 92-94.

84. See, e.g., NATIONAL RESEARCH COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* 28 (1983) (acknowledging that risk assessments always include policy judgments and should therefore not be left to politically unaccountable bodies).

85. For example, if a person is offered a 75% chance at a lifetime income against a 25% chance of losing everything, utility analysis suggests that all but the most aged and wealthy should take the chance. Analogously, a risk assessment combined with a cost/benefit analysis would make a similar recommendation in the case of uncertain technologies such as nuclear power, where a small chance of catastrophic loss must be balanced against great social gains. But, in either of these cases, it is just as rational to avoid taking such a chance, for fear of the small chance of catastrophic loss. Of course, one might influence the risk until the risk was so small and/or the benefit so great, that the vast majority of people would take the risk — or one might vary the risk in the opposite direction.

wide spectrum of rational levels of risk aversion exists, thus implicating the need for political decisions.

Although science can help frame issues, it should not make political choices. While quantitative risk assessment is a valuable scientific aid in regulatory decision-making, it should not be given an "objective" or "neutral" status and be allowed to substitute for the political process. In the area of biotechnology, which evokes many fundamental social values, a purely technocratic solution is singularly inappropriate.

Proponents of quantitative risk assessment are aware of this issue. The NRC acknowledges that within any risk assessment, "a number of decision points occur where risk to human health can only be inferred . . . [and that b]oth scientific judgments and policy choices may be involved in selecting from among possible inferential bridges."⁸⁶ Generally, attempts to address this problem have adopted the NRC's suggestion to differentiate between "risk assessment" and "risk management."⁸⁷ These two regimes are differentiated by the regulatory equivalent of the philosophical "fact/value" distinction.⁸⁸ That is, risk assessment is supposed to be based on objective, factual questions like "how much risk does chemical x present;" whereas risk management is guided by value judgments such as "we do/do not want to live with the level of risk presented by chemical x." But, just as contemporary philosophers question fact/value distinctions, we should question the validity of splitting regulation into risk assessment and risk management.⁸⁹ First, while this distinction might alleviate the

86. *Id.* at 3.

87. *Id.* This approach was quickly embraced by the EPA. See William D. Ruckelshaus, *Risk in a Free Society*, 14 ENVTL. L. REP. (Envtl. L. Inst.) 10,190 (May 1984); U.S. EPA, FRAMEWORK FOR THE FUTURE: RISK ASSESSMENT AND RISK MANAGEMENT AT EPA (1984).

88. The fact/value distinction, like the risk assessment/management distinction, seeks to distinguish an objective, rationally knowable realm from a subjective realm of contingent human values. The distinction was a favorite of a group of philosophers known as logical positivists. See, e.g., ALFRED JULES AYER, LANGUAGE, TRUTH, AND LOGIC (1952).

89. See Milton Russell & Michael Gruber, *Risk Assessment in Environmental Policy-Making*, 236 SCI. 286, 286 (1987) (claiming that the distinction between risk assessment and risk management falters because there is "no 'bright line' between the

baseline problem discussed above (now seen as a problem of risk management rather than assessment), it does not solve the problems raised by risk assessment's need (1) to frame its problems, (2) to decide which aspects of which risks are to be assessed, and (3) to make intermediate "scientific" choices among pessimistic and optimistic models for variables (such as dose-response and exposure level).⁹⁰ Second, risk management is increasingly dominated by "comparative risk analysis," which also has been faulted for ignoring important value choices,⁹¹ and by cost-benefit analysis. Both of these techniques may merely recreate the science/policy problem at a higher level.

A related problem with the Administration's current style of risk assessment is its mistrust of the public's risk perceptions. For example, academic supporters of risk analysis have developed theories relating to faulty risk perceptions among average people under names such as "cognitive error theory."⁹² This intellectual movement has had wide-ranging effects. Most recently, in 1991, EPA Administrator William Reilly unveiled a new Agency effort to base regulatory decisions on "the scientific understanding of risk" rather than on "public risk perceptions."⁹³ His statement was backed by a re-

policy considerations inherent in risk management and those inherent in risk assessment").

90. See *Risk Assessment Guidelines Released by EPA after Prefatory Statement is Added for OMB*, 17 Env't Rep. (BNA) No. 18, at 627 (Aug. 29, 1986), discussing comments made in a letter by Wendy L. Gramm, OMB Administrator of Information and Regulatory Affairs, Letter of Aug. 12, 1986, to Lee M. Thomas, EPA Administrator. Gramm criticized the EPA's cancer risk assessment guidelines on the ground that "[t]he real risk management decision will not be made by regulatory officials, but instead by those involved in the risk assessment process who determine which data to use, which of several scientifically valid models to employ, and which information to reveal." *Id.*

91. See, e.g., Donald Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562, 592-93 (1992).

92. See, e.g., Amos Tversky & Daniel Kahneman, *Judgment under Uncertainty: Heuristics and Biases in JUDGEMENT UNDER UNCERTAINTY 3* (Daniel Kahneman, Paul Slovic, & Amos Tversky eds., 1982). For an excellent discussion of the use of cognitive error theory in risk assessment, see Hornstein, *supra* note 91, at 604-16.

93. *Report of the EPA's Science Advisory Board: Hearing before the Sen. Comm. on Env't and Pub. Works*, 102d Cong., 1st Sess. 45 (1991) (statement of William K. Reilly, Adm'r, EPA).

port by the EPA's Science Advisory Board (SAB),⁹⁴ which asserted the need to "improve the public's understanding of the scientific and technical aspects of environmental risk."⁹⁵ The report left room for considering the public's "deeply held subjective values, like justice and equity,"⁹⁶ a point not dwelt upon by the Administration. Since that statement, however, the Administration has moved even further from the SAB's advice. The Office of Management and Budget (OMB), for example, has recently moved to make comparative risk analysis the first principle of environmental regulation,⁹⁷ a move which would reduce the need for public input even further.⁹⁸

Advocates of risk assessment question the validity of public perceptions, because they believe that the public takes irrelevant factors into account when making risk decisions. The basis of the public's misconceptions is generally believed to be in the use of misleading "heuristics."⁹⁹ In the face of scientific uncertainty, such heuristics, often reflecting deeply held values, deserve more credit.¹⁰⁰ In the case of the environmental release of genetically modified organisms, this is especially true because, due to the infancy of the field and to the consequent lack of negative examples (e.g., Chernobyl), risk assessment is particularly speculative. The public's use of "dread risk"¹⁰¹ as a decision-making factor is thus not *prima facie* irrational. Aspects such as the irreversible or catastrophic potential of a risk, or its consequences for future generations, or the voluntary nature of risk-bearing, are indeed worthy of

94. EPA, SCIENCE ADVISORY BOARD, REDUCING RISK: SETTING PRIORITIES AND STRATEGIES FOR ENVIRONMENTAL PROTECTION (1990).

95. *Id.* at 12.

96. *Id.*

97. *Risk Reduction Initiative in 1992 Proposal Targets DoE, DoD, EPA Environmental Program*, 21 *Env't Rep.* (BNA) 1791, 1796-97 (Feb. 8, 1991).

98. See generally Hornstein, *supra* note 91, at 604-05 (describing this trend in EPA's view of public risk perceptions).

99. Heuristics are "usually speculative formulations serving as a guide in the investigation or solution of a problem." *THE AMERICAN HERITAGE DICTIONARY* 610 (2d College ed. 1982).

100. Hornstein, *supra* note 91, at 604-05.

101. Paul Slovic, *Perception of Risk*, 236 *Sci.* 280, 283 (1987).

consideration by regulatory bodies.¹⁰²

Even if the public's risk perceptions are inaccurate, the Administration's approach is strategically poor, and likely to be perceived as undemocratic in the sense that the public is excluded from decision making. Also, in the absence of massive education efforts, the public is unlikely to adopt the Administration's "scientific" perspective. Thus, the Administration might enter a circle in which administrative "objectivity" engenders increasing public mistrust. For biotechnology, this result is especially likely to occur for two reasons. First, the public might perceive that those who stand to gain most from biotechnology — scientists and industry specialists — as being those who are the most deeply involved in the purportedly objective risk assessment process. Second, in taking decisions further from the public, the Administration will only accentuate the anxiety that naturally results from a perception of risk and a feeling of impotence.

In conclusion, risk-based regulation in the biotechnology context has two strikes against it. First, it fails to take fully into account significant dangers because they are hard to quantify, or because they fall outside its narrow framing procedures. For a new technology like biotechnology, and for one whose risks are likely to be complex, long-term, and synergistic, it is very likely that quantitative risk assessment will underestimate the actual risks. Second, it fails to take public perceptions of risk into account, assuming instead an increasingly adversarial stance toward public perceptions. As Latin notes, in a situation where "good science" is not to be had, a more openly political choice is required, one that should at least balance quantitative risk assessment with public perceptions.¹⁰³

Making quantitative risk assessment the sole basis for biotechnology regulation makes neither practical nor political sense. A regulatory regime built on this approach is likely to increase public anxiety, mask important political choices in purportedly neutral, scientific terms and ultimately, fail to

102. Hornstein, *supra* note 91.

103. Latin, *supra* note 82, at 148.

consider many of the potential hazards presented by biotechnology.

2. The Risk-Based Approach in the Federal Oversight Document

Having discussed the use of risk-based regulation on biotechnology generally, it is also necessary to turn to the Federal Oversight's specific deployment of this approach. This is expressed in the following principle: "[a] determination to exercise oversight in the scope of discretion afforded by statute should be based on evidence that the risk presented by introduction of an organism . . . is unreasonable."¹⁰⁴ Two features differentiate this principle from the approach utilized in the Oversight Principles. First, agencies only act to minimize risks that are unreasonable. The Federal Oversight defines a risk as unreasonable if its cost to society is greater than the cost of regulating it, and thus introduces a cost-benefit analysis into oversight decisions.¹⁰⁵

While this represents a refinement of the Proposed Oversight document, in the sense of recognizing that agencies have more complex alternatives than a binary choice between regulating and not regulating, it also exceeds the Proposed Oversight document in the sense of no longer being primarily about *scope*. Using the "reasonable" standard, the Federal Oversight document constitutes a substantive guide to agency standard setting (presumptively, of course, within the limits of statutory authority). The Federal Oversight document asserts that the "unreasonable risk" definition "enables, and requires, agencies to choose from among the range of oversight options those measures that obtain net benefits."¹⁰⁶

One problem with the Federal Oversight document's more aggressive approach is that agencies regulating risks under various statutes typically already have threshold standards for regulation, many of which are prescribed by statute.

104. Federal Oversight, 57 Fed. Reg. 6753, 6756.

105. *Id.* (agencies must choose regulatory strategies which achieve risk reduction at net benefit and least cost).

106. *Id.* at 6757.

While it may be true, as the Federal Oversight document asserts, that “‘unreasonable risk’ is already a criterion used by federal agencies, such as in exercising oversight under provisions of TSCA and FIFRA,” this ignores the fact that the use of “unreasonable” in such statutes has usually not been construed to mean the narrow cost-benefit interpretation advocated by the Administration.¹⁰⁷ Although the costs of regulations are often included among the factors to be taken into account, they are seldom the sole or controlling factors.

Thus, the mandates of the Federal Oversight document will present agencies with a serious problem: reconciling the statutory thresholds for oversight with those advanced by the Federal Oversight document.¹⁰⁸ Indeed, to the extent it would not directly violate the “within statutory limits” provision, adopting the Administration’s “reasonable” standard might result in biotechnology products being regulated less stringently than conventional products (for which the cost-benefit analysis is only one factor among many).

The second major problem with the Federal Oversight document’s definition of unreasonable risk is that it exacerbates a negative feature of quantitative risk assessment generally: the devaluing of hard to quantify risks — risks that may be particularly relevant in the context of biotechnology.¹⁰⁹ In the previous section, it was shown how quantitative risk assessment tends to underemphasize risks that are not currently well understood, that are cumulative or synergistic, and that take a long time to surface.¹¹⁰

Adding a cost-benefit approach to quantitative risk assessment magnifies the problem because of an imbalance between the ease of determining costs and benefits. Filling out the “benefits of regulation” side of the equation requires

107. See Applegate, *Worst Things First*, *supra* note 80, at 295.

108. This problem was avoided by the Proposed Oversight document which, while being risk based, nonetheless left the determination of the threshold level of risk up to agencies. Proposed Oversight, 55 Fed. Reg. 31,118, 31,120. “Oversight is not required . . . unless information concerning the risk posed by an introduction indicates that oversight is necessary.” *Id.*

109. See *supra* text accompanying notes 80-82.

110. See *supra* text accompanying notes 79-103.

quantifying the risks avoided, as well as a process of valuing the environment, a process that raises a number of difficult problems.¹¹¹ In contrast to the difficulty of quantifying the "benefits" side of the equation, the "costs of regulation" side can be easily quantified as involving the loss of jobs, costs to firms, and administrative costs. Thus, the cost-benefit analysis is likely to devalue the risks involved with biotechnology. This is particularly true when one reflects that uncertain numbers may be more easily manipulated according to underlying values. If the agencies accept the values of the Federal Oversight document, any uncertainty in the calculation of the benefits of regulation will be resolved by choosing the minimum figure.

In attempting to deal with the information costs of regulation, the Federal Oversight document suggests that the uncertainty of risks weighs against regulation. The document does this by specifying that "[a]ny information requests should be designed to maximize their benefits and minimize their costs by soliciting only the most useful information in the least costly manner."¹¹² Because the information gathered on an organism is used to determine the organism's risk, the quantity and quality of such information has a bearing on regulatory decisions. A decision based on cost-effectiveness may limit the information gathered on an organism. Then, on the basis of such limited information, an organism may be deemed to pose a reasonable risk that does not call for regulation. But, while information costs are clearly an important factor, it is not clear that such costs should always be a disincentive for regulation.

Consider the case of toxic tort litigation.¹¹³ In these cases,

111. See *Ohio v. United States Dep't of Interior*, 880 F.2d 432, 438-50 (D.C. Cir. 1989) (discussing alternative methods for valuing harm to natural resources under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), 42 U.S.C. § 9651(c)); see also Frederick R. Anderson, *Natural Resource Damages, Superfund, and the Courts*, 16 B.C. ENVTL. AFF. L. REV. 405 (1989).

112. Federal Oversight, 57 Fed. Reg. 6753, 6757. The document also notes that "[i]f the risk reduction to be gained is small, as will usually be the case with low-level risks, less costly oversight options will need not apply." *Id.*

113. See, e.g., *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988); *Jackson v. Johns-Manville Sales Corp.*, 750 F.2d 1314 (5th Cir. 1985), *cert. denied*,

issues of causation are generally very complex, and weigh against the plaintiffs. We often know in an extrajudicial way that some harm was done, but the scientific evidence does not always live up to the burden established by legal rules. In such cases, imposing high standards of proof has the effect of forcing plaintiffs to bear the information costs. This, in turn, may make it not worth their while to sue. Such a situation may create poor incentive effects, since firms will realize they are at no risk of being held liable, whatever their behavior. Thus the net social result of imposing information costs on the plaintiffs may be negative. In the case of biotechnology, similar concerns must be addressed. Firms should not receive a regulatory subsidy simply because the risks of their products are difficult to precisely determine. A more reasoned approach would be to ask them to participate in generating information needed for accurate regulation.

In conclusion, the "unreasonable risk" threshold for agency oversight is flawed in two respects. First, it promises to be difficult to reconcile with threshold standards already in place under various statutes. Second, because the costs of regulation can be more easily quantified than can the benefits, the approach will tend to exacerbate the bias toward under-regulation already present in quantitative risk assessment. These flaws are particularly evident in the case of biotechnology regulation because of the higher degree of uncertainty concerning the risks of genetically modified organisms.

C. Familiarity as a Basis for Risk Assessment

Having established that the scope of biotechnology oversight will be determined by a risk-based evaluation of biotechnology's products, the Federal Oversight document presents a method for performing the actual risk analysis: "One means of judging the risk posed by an introduction is to compare its risk to an introduction of a comparable organism . . . previously used in introductions in a comparable target environ-

ment.”¹¹⁴ The “comparable organisms” strategy reflects the influence of the NRC report, “Field Testing Genetically Modified Organisms: Framework for Decisions,” which identifies an organism’s “familiarity” as the key factor in assessing its risks.¹¹⁵ Specifically, the proposed framework for decisions specifies three basic questions, ordered as a flow chart such that a “yes” to each question means no regulation is required; whereas, a “no” entails asking the next question. The first question is “are we familiar with the properties of the organism and the environment into which it will be introduced?”¹¹⁶

The familiarity standard has certain advantages. As the report notes, “[i]ts use permits decisionmakers to draw on past experience with the introduction of plants and microorganisms into the environment, and it provides future flexibility . . . as our knowledge increases, entire classes of introductions may become familiar enough to require minimal oversight.”¹¹⁷ Additionally, use of the familiarity standard complements the product over process formula in defending the proposition that there is nothing new about genetically modified organisms. As the Federal Oversight document notes, “[a]n organism can be similar to a previously used organism regardless of the process by which the organism has been modified.”¹¹⁸

But by the same token, this latter statement demonstrates the familiarity approach’s reliance on the two principles criticized above. If one questions the appropriateness of the administration’s narrow concept of “risk-based regulation,” and consequently questions the decision to consider only the products of biotechnology and not the process of manufacture, then the familiarity standard appears to rest on shaky ground. Perhaps the familiarity approach is, like the other two principles, the result of a limited regulatory focus that overlooks the broader implications of the new technology,

114. Federal Oversight, 57 Fed. Reg. 6753, 6757.

115. NATIONAL RESEARCH COUNCIL, *FRAMEWORK FOR DECISIONS*, *supra* note 9, at 5.

116. *Id.*

117. *Id.*

118. Federal Oversight, 57 Fed. Reg. 6753, 6757.

that makes important political decisions look like value-neutral science, and that fails to consider public perceptions.

1. Problems with the Familiarity Strategy

The surprising thing about the familiarity approach is that it not really a method of risk assessment at all, but rather an exhortation to *compare* risk assessments presumably already made. This lends it an air of circularity. On the one hand, the Federal Oversight document suggests that an organism's risk should be judged by comparing it to similar organisms, while, on the other hand, the notion of "comparable" is itself risk based.¹¹⁹ In practice, this approach is likely to lead to the replacement of regulation by risk assessment with regulation by analogy. The result is likely to resemble the children's "rumor" game, where a spoken message is whispered from ear to ear around a circle: each child passes on a message "comparable" to the one she heard, but the end result is often a completely new creation — or to return to our subject matter, a completely new level of acceptable risk.

The concept of familiarity also hides two examples of "arbitrary baselines."¹²⁰ According to Donald Hornstein, "[b]aselines are framing devices that make all the difference in the way society evaluates the acceptability of risk. Yet . . . comparative risk analysts . . . imply an ability to locate the risk baseline in a neutral and sensible manner."¹²¹ The first baseline decision regarding familiarity involves the question:

119. *Id.* at 6753, 6757-58. This can be seen in the document's phrase, "introduction posing comparable risk to a previous introduction." *Id.* This circularity was also present in the Proposed Oversight document. There, risk was to be determined on the basis of an organism's "similarity" to previously introduced organisms. But the document went on to say, "an introduction is considered similar . . . when the level of risk of the introduction is the same as or less than a previous introduction." Proposed Oversight, 55 Fed. Reg. 31,118, 31,120. The Federal Oversight document mentions that some public commentators had pointed to the "potential circularity" in the Proposed Oversight document, Federal Oversight, 57 Fed. Reg. 6753, 6757, and this is presumably why the term "similar" was replaced by "comparable." The circularity, however, remains.

120. Hornstein, *supra* note 91, at 618.

121. *Id.* (discussing the way baseline decisions are often hidden with the objective language of risk analysis).

How similar does an organism have to be to a previously released "comparable" organism? The "Framework for Decisions" report cautions in its analysis that "terms such as 'uncertainty,' 'sufficient,' and 'significant' are used in the framework without precisely defining their quantitative limits. Any specific numerical values assigned would be arbitrary and subject to disagreement, as some underlying variables may be difficult to quantify precisely."¹²² But these are, of course, terms that are central to the determination of an organism's "familiarity." The report also states that, because these terms cannot be quantified precisely, "assignment of risk categories must include a rational examination of the relevant scientific knowledge for each introduction."¹²³ But, scientific knowledge is not what is needed to solve the baseline problem. Questions about, (1) how much "uncertainty" is acceptable, (2) which aspects of an organism are "significant," and (3) how closely related two organisms must be to be considered "similar," all involve value decisions that cannot be resolved by scientific knowledge alone.

This analysis must be applied specifically to the Federal Oversight document. Consider its clear statement of the familiarity-based method: "An introduction should be subject to no greater degree of oversight than was a comparable organism or product previously used in past safe introductions in a comparable target environment."¹²⁴ This principle is meant to apply in cases where the previous introduction involved a non-genetically-modified organism and the current introduction involves a modified one. As to their relative risks, regulators are to follow the principle that "[modified] organisms . . . conferring no greater risk to the target environment . . . should be subject to a level of oversight no greater than that associated with the unmodified organisms."¹²⁵ Note that given the analysis above, the phrase "conferring no greater risk" is

122. NATIONAL RESEARCH COUNCIL, *FRAMEWORK FOR DECISIONS*, *supra* note 9, at 125.

123. *Id.*

124. Federal Oversight, 57 Fed. Reg. 6753, 6757.

125. *Id.* at 6756.

imprecise. Because the determination is based on the methods of quantitative risk assessment criticized above, it will underestimate the cumulative and long term risks that may result from novel organisms.¹²⁶ The comparability determination, employed within the framework suggested by the Federal Oversight document, is likely to have a systematic bias that would tend in the direction of allowing ever more risky organisms to avoid federal oversight.

The familiarity approach presented in the Federal Oversight document would exempt from oversight those organisms that are similar to organisms used in previous "safe" introductions. The second baseline problem derives from the question concerning just how safe the past introductions need be. Although they may all have been classified "safe," there will be, nonetheless, significant differences of absolute risk among them. In linking oversight of genetically modified organisms to the "safety" of previously unregulated releases, the Federal Oversight document's approach avoids the basic question of how much risk society is willing to accept from biotechnology. For instance, because of the newness and uncertainty of biotechnology's risks, it might be decided that a higher standard is appropriate and that new introductions need to be similar not just to previous "safe" introductions, but rather to past "extremely safe" introductions.¹²⁷ The Federal Oversight document's "comparable organism" method of risk assessment hides the fact that the decision concerning the appropriate definition of "safety" is a political question, not a scientific one. A final problem is that the Federal Oversight document does not clarify how the safety of previous releases should be determined. Is it enough that releases of a given organism have not yet led to serious problems, or is a more exhaustive risk analysis necessary? Considering the complexity of ecosys-

126. Cf. Tiedje, et al., *supra* note 6, at 300. "[N]ovel organisms with novel combination of traits are more likely to play novel ecological roles, on average, than are organisms produced by recombining genetic information existing within a single evolutionary lineage". *Id.*

127. This theme will be taken up in the discussion of the "ample margin of safety" requirement of many statutes dealing with toxins, and its relevance to biotechnology regulation. See *infra* notes 156-57 and accompanying text.

tems, coupled with the fact that environmental risks often develop very slowly and are difficult to detect, this is an issue that warrants more consideration than it is given by the Federal Oversight document.¹²⁸

2. The German Approach to Familiarity

It is instructive to contrast the Federal Oversight Document's familiarity approach with biotechnology regulation in Germany. Whereas the American approach seems to be built around the central idea that genetically modified organisms are not new, and are for the most part familiar, the German Parliament seriously considered the idea that biotechnology presents a radically new regulatory challenge.¹²⁹ The Parliament was pushed to draft a law on biotechnology regulation when an administrative court held that the regulatory agency charged with granting permits to biotechnology processing plants had no authority to do so under existing statutes.¹³⁰ The court reasoned that the types of risk presented by the release of genetically engineered organisms were fundamentally new in kind and, since existing statutes therefore did not envision them, the agencies deriving authority from these statutes had no authority to regulate biotechnology. A new legislative norm was required. This ruling prompted the Administration to propose a comprehensive law for the regulation of genetically engineered organisms. After broad, lengthy debate and extensive amendment, the "Gentechnikgesetz" was enacted in March of 1990.

The German experience should make one reconsider the

128. Cf. Tiedje, et al., *supra* note 6, at 305 (discussing the difficulty of accurately determining the safety of a given release, and concluding with respect to the temporal dimension of risk that "the absence of an immediate negative effect does not ensure that no effect will ever occur").

129. The American view is based on our overextension of the product/process formula, discussed *supra* notes 53-73 and accompanying text.

130. Judgement of Nov. 7, 1989, Hessischer Verwaltungsgerichtshof, 8 TH G85/89, Administrative Court of Hessen. Generally speaking, German courts require that legislative delegations of authority to executive agencies be more specific and concrete than American courts do of congressional delegations. See generally RONALD BRICKMAN, ET AL., *CONTROLLING CHEMICALS* 100-28 (1985) (describing different regulatory role of courts in the United States, Germany, Great Britain and France).

easy use of "familiarity" in the Federal Oversight document. In addition to the arguments presented in this section, it suggests that even if one does accept the model of risk-based regulation for the environmental release of genetically engineered organisms, the "familiarity" approach recommended by the Federal Oversight document would leave important factors out of the risk equation. Indeed, since we have chosen once already to de-emphasize biotechnology's unique aspects — by regulating it under statutes not enacted with it in mind — the risk assessment methods used in its regulation should, unlike the familiarity approach, ensure that they are considered.

D. The Category-Based Approach to Biotechnology Regulation

After elaborating a method of risk assessment similar to that developed in the Coordinated Framework document, the tentative Oversight Principles document concluded with a list of "categories of organisms that would generally be excluded from [federal] oversight."¹³¹ As one of the Proposed Oversight document's most controversial features, this list of exemption categories drew a good deal of public comment. As a result, the Federal Oversight document dropped this approach, citing two reasons.¹³² First, the categories given in the Proposed Oversight document were not based on specific risk justifications made under particular statutes (that would have to have

131. Proposed Oversight, 55 Fed. Reg. 31,118, 31,121. These categories were:

1. Plants and animals resulting from natural reproduction or traditional breeding techniques.
2. Microorganisms modified through chemical or physical mutagenesis, or through natural processes of DNA mobility.
3. Plants regenerated from tissue culture.
4. Organisms with insertions of non-coding, non-expressed DNA sequences.
5. Organisms resulting from deletions, rearrangements and amplifications within a single genome.
6. Organisms with new phenotypic traits conferring no greater risk to the target environment than a "safe" parental strain.

Id. Categories 5 and 6 especially went far beyond previous formulations; the BSCC, for instance, had included only categories 1-4 on its draft list. *See id.* at 31,119. Categories 5 and 6 would exempt many organisms which could never have occurred naturally or by traditional breeding methods.

132. Federal Oversight, 57 Fed. Reg. 6753, 6758.

been done before an agency could have adopted them). Second, the categories were based only on organisms, rather than on introductions as a whole (including such factors as the character of the target environment).¹³³

It is a laudable development that the categories presented in the Oversight Principles document (informed as they were by the Competitiveness Council's desire to unburden biotechnology firms) were seen to be a case of too much too soon. However, the Federal Oversight document is far from rejecting a category based approach: it asserts that "the concept of categories for exclusion may nonetheless remain useful in appropriate statutory circumstances."¹³⁴ For example, the Federal Oversight document suggests that under TSCA, the EPA could exclude categories from oversight on the grounds that the organisms composing them presented either no "new" properties or no "unreasonable risk."¹³⁵

This article previously questioned the notions that genetically modified organisms are not "new,"¹³⁶ and also questioned both the sufficiency of biotechnology risk assessment and the use of the Federal Oversight document's definition of "unreasonable risk."¹³⁷ This section addresses the use of this methodology to generate categories of exclusion.

The reason for this analysis is that even if the propositions of product over process, risk-based regulation, and familiarity as the basis for risk assessment are accepted as the

133. These two objections can be generalized to yield the following: the categories were simply too broad to capture the reality of different types of risk, different types of target environments, and different statutory mandates. The following text argues that the Federal Oversight document has not remedied this defect.

134. Federal Oversight, 57 Fed. Reg. 6753, 6759.

135. *Id.* at 6759. TSCA applies to "new chemicals," TSCA §§ 4(9), 5(a)(1)(A), 15 U.S.C. §§ 2602(9), 2604(1)(a)(A) (1988). The Federal Oversight document thus suggests that some genetically modified organisms might not be "new" in this sense because the modification involved resulted in no new phenotypic properties (perhaps the simplest example would be a DNA "marker" insert with no effect on the organism's properties). TSCA provides for regulation of toxic substances which pose "unreasonable risk." 15 U.S.C. §§ 2604(f), 2605(a). It has already been suggested that TSCA's definition of unreasonable risk is by no means the same as that elaborated in the Federal Oversight document. *See supra* note 104, and accompanying text.

136. *See supra* text accompanying notes 114-28.

137. *See supra* notes 104-13 and accompanying text.

basis for biotechnology regulation, using them to generate entire classes of exempt organisms may not be justified. Because the other principles are so little oriented to the "big picture" of biotechnology's cumulative effects, this last step may be the place to introduce a dose of broader vision. This stance is also warranted because the ecological risks at issue are potentially irreversible. As William Hines has written, "in dealing with irreversible destruction of natural environments, the state of the art in [cost-benefit analysis] suggests that it is wise to err on the side of preservation."¹³⁸ Finally, we should be hesitant to employ the exemption approach because regulatory exemptions themselves tend to be irreversible. The D.C. Circuit, in invalidating the EPA's exemption of certain classes of point source water polluters from the permit requirements of the Clean Water Act, addressed this problem, stating that "[a]n exemption tends to become indefinite: the problem drops out of sight, into a pool of inertia, unlikely to be recalled in the absence of crisis or a strong political protagonist."¹³⁹

One argument against developing categories of exempt organisms is based on the observation that this approach will be less responsive to scale effects and to the effects of widespread patterns of use.¹⁴⁰ A major goal of the Federal Oversight document is to avoid burdening the developing U.S. biotechnology industry with regulatory red tape.¹⁴¹ If this effort is successful,

138. N. William Hines, *A Decade of Nondegradation Policy in Congress and the Courts: The Erratic Pursuit of Clear Air and Clean Water*, 62 IOWA L. REV. 643, 652 (1977).

139. *Natural Resources Defense Council v. Costle*, 568 F.2d 1369, 1382 (D.C. Cir. 1977). As an alternative to EPA's exemptions, the court suggested the practice of "general permitting," in which classes of polluting sources in a given region are given five-year permits. While reducing the administrative costs through grouping numerous sources into a single class, this approach keeps the sources in the regulatory system, thus avoiding the possibility that they would "drop out of sight." The general permitting idea will be discussed at length in the concluding section of this article.

140. Cf. Tiedje, et al. *supra* note 6, at 304 (discussing risk effects of varying scales and patterns of use). Note that the size of an introduction is not one of the factors the Oversight Principles takes into account. Federal Oversight, 57 Fed. Reg. 6753, 6757.

141. See Press Release from Council on Competitiveness, Streamlining Federal Regulation of Biotechnology Products (Feb. 24, 1992) (noting that one goal of the Federal Oversight document is to remove unnecessary regulatory barriers to the de-

uses will multiply radically as the biotechnology industry develops and expands. This, in turn, raises the specter of the cumulative effects of individually safe organisms. Past experience with pesticides has made some leery of biotechnology's uncertainties:

Consideration only of the incremental effects of individual chemical pesticides is what has placed us in the current fix, in which the cumulative effects of multiple low-risk toxicants add up to substantial risks. Similarly, it is not just the individual introductions of organisms that deserve attention, but how society chooses to utilize this kind of increased capability to manipulate the environment.¹⁴³

Thus, deregulating individual classes of organisms addresses only the "incremental" effects induced by such organisms. The "cumulative" effects of such organisms are thus removed from regulatory oversight, making it likely that problems arising from these cumulative effects would probably not be addressed until they reached dangerous proportions.

It would be wise to consider the release of genetically modified organisms as a unified and radical human program of recreating our environment to suit our needs.¹⁴³ Thus, regulators should try to track the cumulative and long term effects of the project. However, the regulatory approach based on creating categories of exclusion from oversight directly frustrates such broad tracking. Exempt organisms no longer generate useful information because they are out of a regulator's consideration.

Interestingly, the Administration has moved far beyond the recommendations of many of its advisors in the exclusion-

velopment of biotechnology products).

142. Simon A. Levin, *An Ecological Perspective*, in *THE GENETIC REVOLUTION* 45, 52 (Bernard D. Davis ed., 1991).

143. Courts initially considered the view that the release of genetically modified organisms had a unified, programmatic aspect (with the possibility of cumulative or synergistic effects), see *Foundation on Economic Trends v. Heckler*, 756 F.2d 143, 159-60 (D.C. Cir. 1985), but ultimately adopted the incrementalism characteristic of the Administration's approach.

category approach. For instance, the cumulative effects problem was acknowledged by the National Academy of Sciences in its "Key Issues" report.¹⁴⁴ But, in the years since 1987, it has apparently dropped out of the Administration's view. Furthermore, the Administration has also departed from the "Framework for Decisions" report, inasmuch as that report's recommendations — meant to apply only to small scale field tests — have been extended to apply to *all* introductions without being modified to account for problems of scale.¹⁴⁵ Levin writes, "I am in agreement with the views of the ESA, NAS, and Campbell in supporting small-scale and controlled field tests as a necessary step in getting the products of biotechnology into the field, but in urging caution where large-scale commercial applications are contemplated."¹⁴⁶

Additionally, the category-based approach leaps beyond the "Framework for Decisions" report in another crucial way. Throughout, the report focused on "organisms" rather than on "classes of organisms." It raised the possibility that, within the context of small scale field tests, "[e]ventually, as our knowledge increases, entire classes of introductions may become familiar enough to require minimal oversight."¹⁴⁷ The language used clearly indicates that this is a possibility for the future, one unlikely to have materialized in the short span between the publication of the report and the publication of the Federal Oversight document. Thus, the Federal Oversight document seems to accept too readily the promise of exempting entire classes of organisms from federal oversight.¹⁴⁸

In sum, the type of determinations required by the risk-

144. NATIONAL ACADEMY OF SCIENCES, KEY ISSUES, *supra* note 57, at 20-21.

145. Federal Oversight, 57 Fed. Reg. 6753, 6757 ("not limited to small-scale field trials").

146. Simon Levin, *supra* note 142, at 57; *see also* Tiedje, et al., *supra* note 6, at 304 (also advocating small-scale field testing but expressing more hesitancy where large-scale introductions are at issue).

147. NATIONAL RESEARCH COUNCIL, FRAMEWORK FOR DECISIONS, *supra* note 9, at 5.

148. *Cf.* Tiedje, et al., *supra* note 6, at 307-08 (supporting the category based approach in principle, but finding that there is not currently enough scientific knowledge to accurately define such categories; advocating in the meanwhile the use of case-by-case review).

based familiarity approach are, at the present state of our knowledge, not suited to heavy use of the exclusion category regulatory strategy. The inherent uncertainty in the determination of familiarity, for example, is multiplied when the determination is made for entire categories of organisms. In the case of biotechnology, "case-by-case review is currently the most scientifically sound regulatory approach."¹⁴⁹ Therefore, it would be prudent, at least for the time being, to avoid exempting whole categories of introductions from regulatory scrutiny.¹⁵⁰ Importantly, this does not mean that regulators should not consider the effects of whole categories of organisms. A broader perspective would be wise, yet such a perspective would be impossible under an exclusion-based approach.

149. *Id.* at 307, 310.

150. However, in May of 1992, the FDA announced that it would not promulgate special rules for regulating genetically engineered foods. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (1992). The Council on Competitiveness reportedly lobbied for the FDA to adopt this policy. Warren E. Leary, *Gene-Altered Food Held by the F.D.A. to Pose Little Risk*, N.Y. TIMES, May 26, 1992, at A1.

The policy is the first implementation of the Federal Oversight document; the policy's contours follow the fundamental principles announced by the Federal Oversight document. See 57 Fed. Reg. 22,984, 22,989-91. For instance, in line with the Federal Oversight document's stand on the product/process debate, the FDA has said that genetically engineered foods are not inherently dangerous and, thus, such foods do not require special regulatory attention. 57 Fed. Reg. 22,984, 22,984-85. Second, the policy states that only genetically engineered foods which are not "substantially similar" to naturally occurring foods will require pre-market testing and approval. 57 Fed. Reg. 22,984, 22,985.

This is essentially an application of the "familiarity" inquiry suggested by the Federal Oversight document. But most importantly, the FDA policy is an example of the Federal Oversight document's disregard for public risk perceptions. See *supra* notes 92-103 and accompanying text. This can be seen most graphically in the fact that the FDA policy does not require any special labelling for genetically engineered foods. 57 Fed. Reg. 22,984, 22,991. Thus, consumers are deprived of any chance of making their own decision about whether they wish to accept whatever risks might accompany genetically engineered foods.

An early response to the policy was the Foundation on Economic Trends' boycott of genetically engineered foods by more than 1000 chefs from premiere restaurants. *Chronicle: Genetically engineered foods? Not in their kitchens!*, N.Y. TIMES, July 30, 1992, at B6.

IV. Reforming the Scope of Federal Biotechnology Oversight

Two factors have placed American biotechnology regulation on the wrong track. First, agencies have been forced to regulate biotechnology under statutes that were not enacted with biotechnology in mind. Agencies have been able to make relatively strong jurisdictional arguments for their authority to regulate biotechnology under these statutes, but they have paid a price. Regulatory programs with the most judicial legitimacy are not necessarily the most rational programs for administering biotechnology.

Second, contemporary trends in risk assessment, comparative risk analysis, and the application of cost-benefit analysis to regulation have made our regulatory regime ill-equipped to identify and regulate the risks of large-scale agricultural biotechnology. Because such theoretical trends tend to mask the need for political choices, even in purportedly "objective" regulatory programs, these trends have created a smoke screen that has hidden — rather than solved — the problems created by the lack of specific legislative guidance.

A. Is Legislative Guidance Required?

Would the best solution to these problems be to follow the German example and ask Congress to provide more explicit legislative guidance?¹⁵¹ The Administration is emphatically against this idea,¹⁵² not just because of its adversarial relation to Congress, but also because it senses that popular sentiment (however misguided by improper heuristics) may be against a laissez-faire approach to biotechnology development.¹⁵³ Further inflaming popular sentiment by ignoring the need for a comprehensive regulatory framework for biotechnology, however, is unlikely to be the best approach. In the long run, waiting for a crisis might be worse for the developing

151. See *supra* note 130 and accompanying text.

152. COMPETITIVENESS COUNCIL, *supra* note 1, at 14.

153. See NEW DEVELOPMENTS IN BIOTECHNOLOGY, *supra* note 2, at 45-49.

industry than taking some time now to formulate a more rational regime.

On the other hand, there is no reason to suspect that Congress is better equipped than the Executive to develop a rational regulatory policy for biotechnology. The necessary technical competence and close familiarity with a specialized subject area are much more in the province of administrative agencies. Often, when Congress tries to put too short a leash on administrative discretion, the results are inefficient.¹⁵⁴ John Applegate has tried to solve this dilemma by drawing a more refined distinction between the respective spheres of Congress and agencies.¹⁵⁵ Under Applegate's theory, it is Congress' job to set broad regulatory priorities, which the agencies then have wide discretion to apply in setting their own agendas. The problem with current biotechnology regulation, however, is not that the Administration is unsure of its priorities, but that its regulatory approach itself is simply not suited to biotechnology products.

The strongest reason for legislative intervention is that the current regime of biotechnology regulation is on the wrong trajectory. As biotechnology firms develop and as more firms enter the field, the agencies will only be forced further along this trajectory. This is the type of situation likely to end in a crisis which can often be more damaging to an industry than an extra regulatory burden at the outset would have been. In order to avert this, it might be necessary for Congress to step in. The proposals made below, however, are based on the belief that the Administration and its agencies still have the chance to craft, under existing statutes, a rational biotechnology policy.

B. Proposal for Reformed Principles of Biotechnology Oversight

The Federal Oversight document is an over-arching pol-

154. See generally Erik H. Corwin, *Congressional Limits on Agency Discretion: A Case Study of the Hazardous and Solid Waste Amendments of 1984*, 29 HARV. J. ON LEGIS. 517 (1992).

155. Applegate, *Worst Things First*, *supra* note 80, at 332-34.

icy statement which guides agency regulation of biotechnology products. Remaining within that framework, the following proposals attempt to describe a better approach to both risk assessment and risk management. Specifically, the proposals are an attempt to remedy flaws in the risk-based "familiarity" methodology and the use of such methodology in generating categories of organisms exempt from federal oversight.

1. Broadening Risk Assessment

There are two major problems with the current concept of risk based regulation. First, it systematically underrates "soft" risks, second-order risks, cumulative or global risks, and public risk perceptions. This defect is exacerbated by the Federal Oversight document's use of a cost-benefit definition of "unreasonable risk." Second, in the area of biotechnology, quantitative risk assessment is an uncertain science. As both sides have recognized, this uncertainty involves numerous policy judgements.¹⁵⁶

At the very least, agencies should be instructed to make more explicit the policy implications of "purely scientific" risk assessment practices. Moreover, agencies should compensate for the limitations of quantitative risk assessment and cost-benefit analysis. They can do this in two ways. First, recognizing that the risks presented by genetically modified organisms are indeed different than the risks presented by hazardous chemicals, they should use risk assessment procedures which are better adapted to the complex interaction of ecosystems over time. Second, in situations where risk assessment leads to uncertainty, precisely the factors left out by quantitative risk assessment should be given more weight. Specifically, given the potential for catastrophic or irreversible risks, the public perception of "dread" risk, and Congress' general conservatism on toxins in most statutes under which biotechnology is regulated,¹⁵⁷ the policy bias when the risk level is uncertain

156. Compare Latin, *supra* note 82 (asserting that quantitative risk assessment hides substantial bias toward under-regulation), with Gramm, *supra* note 90 (OMB officer complaining that EPA risk assessment hides bias toward overregulation).

157. See Latin, *supra* note 82, at 135-36. This is evident in Congress' frequent

should favor considering, rather than ignoring, hard to quantify risks.

The two failings of current risk assessment suggest that the process should be broadened to take better account of the types of risk common to biotechnology products. Also, to the extent that the substantial uncertainty cannot be resolved in a given case, the policy arguments favor a more pro-regulatory stance than is currently being used.

2. Shifting the Costs of Uncertainty

As a corollary, these reforms would lead to a new position on the product-process debate. The current position, that there is "nothing new" about the products of genetic engineering, would have to be softened — although not to the extent that genetic engineering would be considered risky per se. Rather, biotechnology products would face a more stringent burden in proving their safety.¹⁵⁸ This burden would be a direct consequence of the reforms in risk assessment sketched above. If these reforms were enacted, the biotechnology industry would pay a higher price for uncertainty: to the extent that assessments of biotechnology products' safety remained uncertain, the policy considerations mentioned above would weigh in favor of regulation rather than deregulation.¹⁵⁹

use of the "ample margin of safety" requirement in these statutes. Requiring agencies to establish standards with an ample margin of safety is tantamount to requiring that, where risk assessment for a given substance leads to uncertainty, an agency's bias should be to regulate, rather than ignore, the substance.

158. Cf. Tiedje, et al., *supra* note 6, at 310-11 (recommending modified product over process formula, under which products of genetic engineering will often receive closer scrutiny than non-modified organisms); see also Shapiro, *supra* note 19, at 24-25 (discussing problems with the EPA's regulation of biotechnology under TSCA, where the EPA has the burden of proving an organism's danger, as opposed to industry having the burden of proving an organism's safety).

159. Since its restrictive beginnings with the 1976 NIH Guidelines, the history of biotechnology regulation has been a history of steadily moving the burden of dispelling uncertainty onto potential regulators. Compare Guidelines for Research on Recombinant DNA Molecules, 41 Fed. Reg. 27,902, with Federal Oversight, 57 Fed. Reg. 6753. The Federal Oversight document is the current high-water mark in this direction. Federal Oversight, 57 Fed. Reg. 6753, 6757-58. The trend is also evident in the courts. Compare *Foundation on Economic Trends v. Heckler*, 756 F.2d 143 (D.C. Cir. 1985) (uncertainty weighs against those wishing to release organisms) with *Founda-*

Such a regime would have the further beneficial effect of inducing firms to pool their resources in order to generate the scientific data needed to demonstrate their products' safety.¹⁶⁰ This would be beneficial because: (1) firms would internalize some of the government's information costs in regulating their products, (2) firms are usually in a better position to generate reliable data on products with which they have extensive experience, and (3) firm pooling of information gathering resources would tend to facilitate a "big picture" approach that took account of biotechnology's effects across the board.

3. Modifying the Familiarity Approach

This modified product-process approach should also affect the familiarity inquiry. An analogy to past, safe introductions constitutes a reasonable basis for regulation, but it relies on at least two important policy questions that are currently unanswered: (1) how similar does a proposed introduction have to be to a past introduction and (2) how safe does the past introduction itself have to be? To the extent that each of these inquiries is ignored, the danger appears that risky biotechnology products will gradually progress into widespread use simply because no disaster has yet occurred.

Two steps can be taken to reform the familiarity approach. First, it should not be substituted completely for a method of risk assessment based on calculating an introduction's absolute risk, independent of its similarity to other introductions. Risk assessment should not proceed only by analogy. This principle is especially important in an industry like biotechnology, where new organisms are developed at a rapid pace, but their effects may not be felt for many years. The

tion *Economic Trends v. Thomas*, 637 F. Supp. 25 (D.D.C. 1986) (uncertainty weighs against those opposing release) and *Foundation on Economic Trends v. Thomas*, 661 F. Supp. 713, 718 (D.D.C. 1986) (parties opposing release may no longer have standing because of uncertainty of alleged risk). See also Stewart, *supra* note 76, at 223-24.

160. See generally *HARNESSING SCIENCE FOR ENVIRONMENTAL REGULATION* (John D. Graham, ed., 1991) (discussing the Chemical Industry Institute of Toxicology (CIIT) and the Health Effects Institute (HEI), both industry-funded groups which generate scientific data used in regulation, and claiming that such groups will play a larger role in the coming years).

combination of these two factors means that only a method of risk assessment based on some absolute standard will be able to provide a guarantee of safety.

Second, to the extent comparability determinations between two introductions contain uncertainty, an attempt should be made to minimize the progressive accumulation of uncertainties described above.¹⁶¹ This could be achieved by establishing relatively stringent standards for acceptable levels of uncertainty and by evaluating the level of uncertainty for two introductions in light of the absolute level of safety for the previous "safe" introduction.

4. Reforming Risk Management

The foregoing methodological recommendations would require that regulators be more responsive to (1) the types of risk presented by biotechnology, (2) the uncertainty surrounding undertaken risks, and (3) public perceptions of these risks. The remaining part of this proposal addresses the remaining question: how should this new methodology be used in determining the scope of oversight?

On the one hand, given the uncertainties involved, the possibility of irreversible environmental damage, public anxiety, and the lack of support from some of the Administration's own scientific advisors, the strategy of exempting whole categories of genetically modified organisms from oversight seems rash. Indeed, the Federal Oversight document acknowledged that this strategy is problematic, but the document did not abandon the strategy. On the other hand, as The President's Council on Competitiveness notes, we stand to lose a great deal from an overly restrictive regime.¹⁶² In many cases, stringent case-by-case review would impose unjustifiable costs on a fledgling industry, an industry that is likely to contribute greatly to international competitiveness. The Federal Oversight document seeks to avoid this possibility by replicating the narrow framing procedures of quantitative risk assessment

161. See *supra* notes 119-26 and accompanying text.

162. See COMPETITIVENESS COUNCIL, *supra* note 1, at 11.

at the level of risk management through the cost-benefit interpretation of reasonable risk. This, however, results in a gross overcompensation.

A compromise could be achieved with a system of general permitting. In such a system, the risk assessment methodology described above would be used to rank categories of organisms according to risk. Categories that did not appear to pose substantially greater risk than categories of unmodified organisms that previously had been released safely (i.e., the comparability inquiry) would be made into general permit categories.¹⁶³ These categories would be exempt for the period of the permit from further statutory requirements, but they would not be overlooked as would be the case under the Federal Oversight document. The permits could serve a significant "information-forcing" function. For instance, they could be used as probationary periods during which firms would be required to show the safety of releases in their particular category. If at the end of a period, a firm could not make such a showing, that category would be subject to more stringent regulation.

The general permitting approach has the advantage of allowing "safe" introductions to proceed without further regulatory processing, but at the same time it would allow the Administration to maintain a continual monitoring ability over these organisms. A further advantage is that such monitoring would not be limited to individual organisms, but would also consider the effects of classes of organisms. This broader focus would help in the assessment of the cumulative effects of biotechnology, a crucial function that the current regime is unable to carry out.

163. Although it is impossible to predict the results of the revised risk assessment recommended here, it is likely that the general permit categories would be narrower than the exemption categories suggested by the Oversight Principles. Specifically, categories 5 (non-coding regulatory regions) and 6 (inter-generic combinations similar to safe organisms) might not pass muster, or would pass only in narrower form.

5. Expanding the Role of the Biotechnology Science Coordinating Council

This scheme would require a strong contribution from the Biotechnology Science Coordinating Council (BSCC). Agencies would gather data on general permit classes under relevant statutes and would then pass the information on to the BSCC for synthesis. If the BSCC found that a given category of organisms had unanticipated adverse effects, either in individual cases or cumulatively as a group, the BSCC could recommend non-renewal or revocation of that group's permit. If a particular subgroup of organisms was the source of trouble, the BSCC could call for a redefinition of the permit category.¹⁶⁴

A reinvigorated BSCC¹⁶⁵ will be more necessary as biotechnology firms emerge and as their products begin to put more pressure on a statutory framework not designed specifically with them in mind. By giving the BSCC a stronger role as analyst of the cumulative, class-by-class, effects of biotechnology, it is more likely that the coordinated framework will be able to cope successfully with the increased pressure.¹⁶⁶ With a central oversight body, it is also less likely that we will experience a disastrous accident due to biotechnology's broader, cumulative effects. And finally, if the new BSCC were to put itself in closer touch with the public,¹⁶⁷ it would provide an ideal way to increase the public legitimacy of biotechnology regulation at the most global stage of the process.

164. The BSCC's recommendations would not be binding on agencies; rather, they would provide an informational basis upon which the administration (most likely OMB) could base an executive policy that would guide agency action. Under this conception, the BSCC's function is not to impose policy, but to synthesize inter-agency information into a basis for policy decisions.

165. See Sidney A. Shapiro, *supra* note 19, at 32-36.

166. See generally NEW DEVELOPMENTS IN BIOTECHNOLOGY, *supra* note 2, at 28-29 (discussing possibility of interagency task force for generating data on the safety of environmental releases of modified organisms).

167. See generally Sidney A. Shapiro, *supra* note 19, at 54-58 (discussing strategies for increasing public participation in biotechnology regulation). While Professor Shapiro's discussion is organized around the strategic goal of "greater public acceptance of new technologies," it is also possible to view public participation as an end in itself.

V. Conclusion

Current biotechnology policy, exemplified by the Federal Oversight document, is on the wrong track. This is not to say that its anticipated destination (increased domestic productivity and international competitiveness) is an unworthy goal. But in the long run, this goal will only be reached through a rational regulatory policy. As is all too well known, catastrophic accidents in the world of high technology, even if highly unlikely, can lead to legitimization crises that dangerously impede or even halt an industry's development. A reformed Federal Oversight document, as sketched in this article, constitutes a regulatory approach better suited to the unique risks posed by biotechnology — one more likely to enjoy public credibility and less likely to allow such crises to occur.